K060761

Akers Biosciences, Inc.
BreathScan® Alcohol Detector
510(k) Notification

SECTION 5. 510(k) SUMMARY STATEMENT

5.1 Date: April 25, 2006

5.2 Submitter:

Name: Akers Biosciences, Inc

Address: 201 Grove Road

Thorofare, New Jersey, 08086

Telephone: 856-848-8698

Contact: Barbara Bagby

5.3 Device:

Trade or Proprietary Name: BreathScan® Alcohol Detector.
02, .04, .05 and .08% BAC Sensitivity Cut-0ffs

Other Brand Names: Biotech Redwood, EZ Screen, Alco Limit, and Breath Alcohol

Common or usual Name: Breath-alcohol test

Classification Name: Devices, Breath Trapping, Alcohol

Product Code: DJZ

Regulation Number: 862.3050

5.4 Predicate Device:

BreathScan is equivalent to: CONNECTABLES® Alcohol Tester manufactured by Connectables, LLC in Waukegan, IL (K052448).

5.5 Indications for Use

The BreathScan® Alcohol Detector is an *in vitro* medical device to qualitatively detect the presence of alcohol in the human breath. It is a disposable screening device for one-time use. The detector is available at several detection cut-offs: 0.02, 0.04, 0.05, and 0.08 percent breath alcohol. The device is used only as a screening device and is only an indication of the possible presence of alcohol in the blood of the test subject. Correlation between breath alcohol content and blood alcohol content depends on many variables. BreathScan is not intended to legally determine blood alcohol presence, level, or inference of intoxication.

5.6 Description of the device

The BreathScan® Alcohol Detector (Tester) is a visual qualitative test for alcohol in human breath. The Tester contains chemicals that change color in the presence of alcohol vapors) utilizing the patented technology (4,740,475). The Tester is made up of a 2-part glass vessel inside a plastic tube. One part contains light yellow crystals that change color when exposed to alcohol vapors. The other part is an opening to blow into while running the test.

If alcohol is present, the crystals will change from yellow to light green/blue. How many crystals turn color will depend on the cut-off of the Tester and how much alcohol is in the breath.

The yellow crystals in the Tester are coated with potassium dichromate ($K_2Cr_2O_7$) and sulfuric acid (H_2SO_4). The amount of these indicator chemicals is adjusted according to the selected cutoff of the Tester. A color change is produced when alcohol vapors are oxidized to acetic acid and the indicator chemicals change to chromium sulfate [$Cr_2(SO_4)_3$]. The majority of crystals change from yellow to light aqua (greenish-blue/bluish-green) when alcohol vapors are present at a level equal to or exceeding the cutoff of the Tester.

The BreathScan® Tester is available in several cut-offs (.02%, .04%, .05%, and .08%). The cut-off is printed on the Tester label and is expressed as a specific percentage of breath alcohol.

5.7 Safety and Effectiveness

The results of bench and user testing indicates that the new device is as safe and effective as an evidentiary breath test, the ALCO SENSOR IV manufactured by Intoximeters, Inc. which is a DOT/NHTSA approved device (Conforming Products List of Evidentiary Breath Measurement Devices – FR/Vol.69, No.134/July 2004/Notices/42237. Multiple user studies were performed to establish that the user could read and understand the directions provided and properly use the device (Table 1).

Table 1
Comparison to Evidentiary Breath Test (Alco-Sensor IV)

	Predicate Results			
BreathScan® .04% Tester Result	**Less** than 60% below the Cutoff < 0.016%)	**Near Cut-off Negative** (0.016 to 0.040%)	**Near Cut-off Positive** (>0.040 to 0.064%)	**High Positive** (> 0.064%)
Positive	0	0	15	10
Negative	37	25	5	1

Additionally, the BreathScan® Alcohol Detector was evaluated and found to meet the guidelines provided in the DOT/NHTSA Model Specifications for Alcohol Screening Devices –(Federal Register/ Vol. 59, No. 147, August 2, 1994 / Notices/39382) with one exception. This exception was that 1 false positive reading out of 1200 readings of the .04 tester that did not contain alcohol.

5.8 Substantial Equivalence

Similarities and Differences Between BreathScan® and CONNECTABLES®

SIMILARITIES		
Parameter	**BreathScan®**	**CONNECTABLES®**
Indications for Use	Detect the presence of alcohol in the human breath.	Detect the presence of alcohol in the human breath.
Target Populations	Over the Counter	Over the Counter
Calibration/Accuracy Checks	None required	None required
Anatomical Site	Mouth	Mouth
Test Sample	Human breath	Human breath

DIFFERENCES		
Parameter	**BreathScan®**	**CONNECTABLES®**
Result	Qualitative	Semi-Quantitative
Interpretation	Visual Color Change	Red, Yellow, and Green LEDs
Instrument system	None	Semiconductor-Oxide Sensor
Measurement Range	Separate devices are pre-calibrated to turn color at different cut-offs: .02%, .04%, .05%, and .08%	Upper limit undefined – any concentration greater than 0.04% will produce red light
Mouthpiece	None required	Replaceable
Blowing Time	12 seconds	3 seconds
Warm Up Time	None	5-15 seconds
Size	2 ¾ by 1/3 inches	2.1 by 1.64 inches
Weight	1.9067 grams	42 grams
Power Requirement	None	2-AAA alkaline batteries

5.9 Conclusions

After analyzing bench test and user testing data, it is the conclusion of Akers Biosciences, Inc. that the BreathScan® Alcohol Detector is as safe and effective as the predicate and comparative devices. Users studies showed that the over the counter purchaser of this device could read and understand the instructions, could properly use the device and obtain results that were comparable to those provided by a predicate device administered by a trained technician.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 28 2006

Ms. Barbara Bagby
Director Regulatory Affairs
Akers BioSciences, Inc.
201 Grove Road
Thorofare, NJ 08086

Re: k060761
Trade/Device Name: BreathScan Alcohol Detectors (0.02, 0.04, 0.05 and 0.08% BAC)
Regulation Number: 21 CFR 862.3050
Regulation Name: Breath-alcohol test system
Regulatory Class: Class I
Product Code: DJZ
Dated: March 17, 2006
Received: March 22, 2006

Dear Ms. Bagby:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060761

Device Name: BreathScan® Alcohol Detector

Indications For Use:

The BreathScan® Alcohol Detector is an in vitro medical device to qualitatively detect the presence of alcohol in the human breath. It is a disposable screening device for one-time use. The detector is available at several detection cut-offs including 0.02, 0.04, 0.05, and 0.08 percent breath alcohol. The device is used only as a screening device and is only an indication of the possible presence of alcohol in the blood of the test subject.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K060761